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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,803

07/14/2003

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98.22US-CON

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11/18/2009

EXAMINER

FISHER, ABIGAIL L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/618,803	Applicant(s) NAJDEK ET AL.	
	Examiner ABIGAIL FISHER	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7-24 is/are pending in the application.
- 4a) Of the above claim(s) 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/30/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Amendments/Remarks filed on April 1 2009 and supplemental response filed on 8/6/09 is acknowledged. Claim 6 was/stands cancelled. Claims 1-5 and 7-24 are pending. Claims 23-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/16/06.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/30/08 was considered by the examiner.

Response to Supplemental Response

In the reply filed on August 6 2009, applicants' indicated that the examiner did not give a clear rational as to the reason for requiring a complete listing of the claims. In response to this the examiner direct applicants' attention to page 2 of the Office action mailed on 11/21/08 wherein the examiner objected to claims 23-24 as the status of the claims were indicated as withdrawn however no text appeared. In the response filed on

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April 1 2009, the applicant did not correct the issue with claims 23 and 24. Therefore, a notice of non-responsive was deemed necessary as applicants had not and continued to not correct the issue associated with claims 23 and 24. The notice of non-compliant directed applicants to the first response in which no text appeared for claims 23 and 24 in order to aid them in correcting the issue.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-5, 7-9 and 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (WO 92/09266, cited on PTO Form 1449) in view of Nagy et al. (US Patent No. 5871758, cited in the Office action mailed on 12/28/07) as evidenced by Sakellariou et al. (Colloid Polym. Sci. 1995).

Applicant Claims

Applicant claims a dual phase liquid cosmetic or pharmaceutical composition comprising an aqueous phase and an oil phase, each phase being separate from the other except when mixed at the time of use, comprising the step of adding to one of the phases of the composition as a demixing agent an effective amount of a non-cationic film forming agent.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Davis et al. is directed to two-component pharmaceutical compositions for topical application. The composition comprises two distinct phases wherein at least one contains a drug dissolved therein. The phases each have a different liophilicity (page 2, lines 1-6). It is taught that duration of the supersaturated state is limited by evaporation taking place after the phases mix together (page 2-3, lines 34-36 and 1-2). The two phases are intended to be mixed together on or immediately prior to application (page 4, lines 1-5). It is taught that the two phases are physically and/or chemically different

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(page 4, lines 7-9). The proportion of first liquid phase to the second is from 1:1 to 1:12 (page 5-6, lines 34-35 and 1-2). It is taught that water is a necessary component of the second liquid phase (page 6, lines 17-19). The first liquid phase comprises more than one liquid that is generally more lipophilic or less-polar (column 6, lines 20-22). The compositions include anti-nucleating agents such as polyvinylpyrrolidone (example 1, 5, and 6) in an amount up to 10% by weight (page 8, lines 14-27). It is taught that the choice of anti-nucleating agent can readily be selected by simple experiment. For example preparing samples of the desired final supersaturated drug solution (i.e. mixed solution) and then adding the anti-nucleating agent allowing the samples to stand for say 2 hours and noting which solutions remain clear (i.e. phases separate) (page 9, lines 1-8). It is taught that the compositions of the invention are suitable for any medical, cosmetic or other treatment of the body surface (column 10, lines 14-20). The composition may comprise a variety of drugs (page 11, lines 8-17).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Davis et al. do not teach that the first liquid phase comprises an oil, although Davis et al. do teach it is generally more lipophilic or less-polar than water. However, these deficiencies are cured by Nagy et al.

Nagy et al. is directed to dual phase cosmetics. It is taught that the compositions can be utilized as a liquid dual phase makeup removal composition (claim 15) or for therapeutic purposes (column 3, lines 66-67). It is taught that these compositions provide a broad range of cleansing/conditioning potential within a single product (column 1, lines 10-12). It is taught that oil soluble actives may be unstable if in

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prolonged contact with the aqueous phase (column 1, lines 42-44). It is taught that the oil phase may be any cosmetically or pharmaceutically acceptable oil (column 3, lines 18-21). It taught that a in preferred embodiment the oil phase comprises a combination of both volatile and non-volatile oil. The amount of volatile oil used is higher than non-volatile oils. One specific combination is volatile silicone and volatile paraffin. A specific combination is cyclic silicone at 25-40% by weight, C₁₆ isoparaffin in 15-30% by weight and the non-volatile silicone at 0.1 to 1% by weight. A preferred non-volatile silicone is dimethicone. One other exemplified oils include isohexadecane. Other hydrocarbons listed as suitable include decane, dodecane, tridecane, tetradecane, etc. (column 3, lines 29-30).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Davis et al. and Nagy et al. and utilize oils in the first liquid phase. One of ordinary skill in the art would have been motivated to utilize oils as Davis et al. teach two phase compositions that can be utilized for any medical, cosmetic or other treatment of the body surface and the first phase is one that is generally more lipophilic or less-polar. Nagy et al. teach dual phase compositions that are utilized for cosmetic or pharmaceutical purposes that provide a broad range of cleansing/condition potential within a single product. Therefore, one of ordinary skill in the art would have been motivated to utilize the oils taught by Nagy et al. in the composition of Davis et al. One of ordinary skill in the art would have been motivated as both are directed to similar products with similar uses and Nagy teach that these dual phase compositions provide

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a broad range of cleansing/conditioning potential. Furthermore, one of ordinary skill in the art would have been motivated to utilize a oil depending on the active utilized. If a more oil soluble active was utilized in the composition then one of ordinary skill in the art would have been motivated to utilize an oil as taught by Nagy et al.

Regarding applicants claim that the polyvinylpyrrolidone is a demixing agent; Davis et al. do not utilize this particular verbage. However, it is taught that the choice of anti-nucleating agent, of which PVP is one choice, can readily be selected by simple experiment. For example preparing samples of the desired final supersaturated drug solution (i.e. mixed solution) and then adding the anti-nucleating agent allowing the samples to stand for say 2 hours and noting which solutions remain clear (i.e. phases separate). Furthermore, as evidenced by Sakellariou, PVP is known in the art to cause phase separation (abstract, page 287, left column, second paragraph).

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. in view of Nagy et al. as evidenced by Sakellariou et al. in further view of Smith (US Patent No. 5658559, cited on PTO Form 1449).

Applicant Claims

Applicant claims that the film forming agent is polyvinylpyrrolidone hexadecane copolymer.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Davis et al., Nagy et al, and Sakellariou et al. are set forth above. Specifically, Davis et al. teach two-component preparations. It is taught that duration of the supersaturated state is limited by evaporation taking place after the phases mix together. Nagy et al. teach dual phase compositions comprising oil. Sakellariou et al. teach that PVP is known in the art to cause phase separation.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Davis et al. do not specify that the polyvinylpyrrolidone polymer is polyvinylpyrrolidone hexadecene. However, this deficiency is cured by Smith.

Smith is directed to lotions for the treatment of a skin disease or disorder. It is taught that these compositions comprise a barrier polymer to prevent evaporation loss of moisture from the skin (column 4, lines 8-11). Useful polymers include polyvinylpyrrolidone, copolymers of vinylpyrrolidone and eicosene, copolymers of vinylpyrrolidone and hexadecane, etc. (column 4, lines 15-32).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Davis et al., Nagy et al. and Smith and utilize copolymers of vinylpyrrolidone and hexadecane (PVP/hexadecane). One of ordinary skill in the art

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would have been motivated to utilize this polymer as Smith teaches that it prevents evaporation loss of moisture from the skin and Davis et al. teach that evaporation determines the duration of the supersaturated state. Furthermore, one of ordinary skill in the art would have been motivated to replace polyvinylpyrrolidone with copolymers of vinylpyrrolidone and hexadecane (PVP/hexadecane) as both are taught by Smith as functional equivalents.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that (1) the examiner misinterprets, “which samples remain clear” to mean that the phases separate but one skilled in the art would appreciate that “which samples remain clear” refers to which samples remain in the supersaturated or mixed state; that is where the drug remains supersaturated in the mixture and does not precipitate out. Applicants argue that (2) the disclosure in WO ‘266 would indicate that PVP is a stabilizing agent. Applicants argue that (3) the ‘758 (Nagy et al.) teaches utilizing a specific class of cationic surfactants which act as a demixing agent and does not suggest the instant disclosed film formers. Applicants argue that (4) WO ‘266 is not at all concerned with compositions which are mixed temporarily at the time of use and rapidly demixed.

Applicants' arguments filed April 1 2009 have been fully considered but they are not persuasive.

Regarding applicants first argument, while the examiner does agree with applicants statement remain clear does not necessarily mean phase separation, the examiner disagrees with applicants that it necessarily remains in the mixed state. WO '266 teaches that the polyvinylpyrrolidone would be expected to help maintain the drug in solution. This does not necessarily mean that when two phases with different lipophilicities are mixed that they do not separate out.

Regarding applicants second argument, the examiner disagrees. PVP would be interpreted as helping to have the drug remain in solution and therefore not precipitate out. This does not mean that PVP would be interpreted as helping the composition to remain in a mixed state. Furthermore, the examiner cited Sakellariou to show that it is known that PVP causes phase separation. Therefore, while one of ordinary skill would reasonably expect that PVP would help aid in drug solubilization, one of ordinary skill would not necessarily expect the two phases to remain in a mixed state.

The instant claims recite a composition comprising an aqueous phase and an oil phase wherein the composition contains a film forming agent (PVP is a specific agent claimed). WO '266 specifically teaches adding PVP to one or both of the phases of the two phase compositions. The two phases of the compositions of WO '266 would not remain in a mixed state forever, at some point the phases would separate. Instant claim 1 just requires that the phase be separate prior to mixing. Instant claim 8 requires that the phases are separate before and after being mixed at the time use, however there is

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no time frame for this particular separation to occur. Therefore, any time frame would read on instant claim 8.

Regarding applicants' third argument, while the examiner agrees that Nagy et al. teach utilizing different demixing agents than instantly claimed, Nagy et al. is not utilized for its teachings of demixing agents. It is utilized to show that it would have been obvious to one of ordinary skill in the art to utilize an oil in the composition of WO '266.

Regarding applicants' fourth argument, firstly it is noted that the features upon which applicant relies (i.e., mixed temporarily and rapidly demixed) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicants argue that their motivation for utilizing PVP is entirely different than the motivation provided by the examiner or WO '266. Applicants argue that therefore the prior art is not directed to the problem discovered by applicants. In response to this argument, the examiner maintains that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The examiner maintains that based on the teachings of WO '266 and Nagy et al. one of ordinary skill in the art would have been motivated to add an oil in order to provide a broad range of cleansing/condition potential within a single product and aid in solubilization of oil actives. Note: MPEP 2144. "The reason or motivation to modify the reference may often suggest what the inventor has done but for

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a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant". Therefore, while the combination of WO '266 and Nagy et al. would suggest adding PVP to a two phase composition comprising oil and water for a different reason than applicants, the art would suggest this combination.

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments to overcome the rejection.

Double Patenting/Terminal Disclaimer

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection claims 1-6 and 7-24 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No.

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6649174 is **withdrawn** in light of Applicants' filing of a terminal disclaimer in the reply filed on 4/1/09.

The terminal disclaimer filed on 4/1/09 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6649174 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Mina Haghighatian/
Primary Examiner, Art Unit 1616